IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH and BAYER PHARMA AG	)	
Plaintiffs,	)	C. A. No. _____
vs.	)	
	)	**JURY TRIAL DEMANDED**
WARNER CHILCOTT COMPANY, LLC, WARNER CHILCOTT (US), LLC, and WARNER CHILCOTT PLC	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer Intellectual Property GmbH and Bayer Pharma AG (together "Bayer") bring this Complaint for patent infringement against Defendants Warner Chilcott Company, LLC, Warner Chilcott (US), LLC, and Warner Chilcott PLC (collectively "Warner Chilcott") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, including 35 U.S.C. §§ 271, 281-285.

2. This lawsuit pertains to Warner Chilcott's infringement of U.S. Patent Number 5,980,940 (the "'940 Patent"). A true and correct copy of the '940 Patent is attached hereto as Exhibit A.

3. United States Patent No. 5,980,940 issued on November 9, 1999. Inventors Jürgen Spona and Bernd Düsterberg filed their application for this patent on April 4, 1996. Bayer Pharma AG is the current owner of the '940 Patent.

PARTIES

4. Plaintiff Bayer Intellectual Property GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 10, 40789 Monheim, Germany.

5. Plaintiff Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business in Müllerstrase 178, 13353 Berlin, Germany.

6. On information and belief, Defendant Warner Chilcott Company, LLC is a limited liability company organized and existing under the laws of Puerto Rico, having a principal place of business at Union Street, Road 195, Km1.1, Fajardo, PR 00738-1005. On information and belief, Warner Chilcott Company, LLC is in the business of, among other things, developing, manufacturing, marketing and selling branded prescription pharmaceutical products in women's healthcare and dermatology in the U.S.

7. On information and belief, Defendant Warner Chilcott (US), LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 100 Enterprise Drive, Suite 280, Rockaway, NJ 07866. On information and belief, Warner Chilcott (US), LLC is in the business of, among other things, developing, manufacturing, marketing and selling branded prescription pharmaceutical products in women's healthcare and dermatology in the U.S. On information and belief, Warner Chilcott (US), LLC is a wholly-owned subsidiary of Warner Chilcott PLC.

8. On information and belief, Defendant Warner Chilcott PLC is a company organized and incorporated under the laws of Ireland, with its corporate headquarters located at 1 Grand Canal Square, Docklands, Dublin 2, Ireland. On information and belief, Warner Chilcott

PLC is in the business of, among other things, developing, manufacturing, marketing and selling branded prescription pharmaceutical products in women's healthcare and dermatology.

JURISDICTION AND VENUE

9. This action arises under the Patent Laws of the United States, 35 U.S.C. § 101 *et seq.*, including 35 U.S.C. § 271. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1338(a).

10. This Court has personal jurisdiction over Warner Chilcott. Warner Chilcott (US), LLC is incorporated in Delaware and maintains substantial, continuous, and systematic contacts in Delaware. Warner Chilcott (US), LLC has thus purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being sued in this jurisdiction. Warner Chilcott PLC is subject to personal jurisdiction in Delaware because, on information and belief, Warner Chilcott PLC controls and dominates Warner Chilcott (US), LLC, and therefore the activities of Warner Chilcott (US), LLC in this jurisdiction are attributed to Warner Chilcott PLC. Warner Chilcott Company, LLC is subject to personal jurisdiction in Delaware because Warner Chilcott Company, LLC manufactures pharmaceutical drugs with the knowledge and intent that Warner Chilcott Company, LLC's drugs will be sold in the United States, including within Delaware, by Warner Chilcott (US), LLC. Warner Chilcott Company, LLC has thus engaged in systematic and continuous business contacts within Delaware, and has therefore purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being sued in this jurisdiction.

11. Venue is proper in the District of Delaware pursuant to 28 U.S.C. §§ 1391, 1400(b).

FACTUAL BACKGROUND

12. Plaintiff Bayer Intellectual Property GmbH is the assignee of the '940 Patent.

13. Plaintiff Bayer Pharma AG holds an exclusive license under the '940 Patent.

14. The '940 Patent claims a pharmaceutical combination preparation with two hormone components, whereby the first hormone component compromises 23 or 24 daily units and the second hormone component comprises 4, 3, or 2 daily units. Between the two hormone components, 2 or 1 active ingredient-free daily units are present.

15. Defendant Warner Chilcott sells Lo Loestrin tablets in the United States as a 28-day oral contraceptive regimen. Lo Loestrin contains 24 tablets comprising 1mg norethindrone acetate and 10 mcg ethinyl estradiol, 2 tablets comprising 10 mcg ethinyl estradiol, and 2 ingredient-free tablets.

16. Defendant Warner Chilcott has listed its U.S. Patent No. 7,704,984 (the "'984 Patent") in the Orange Book for Lo Loestrin. The '984 Patent claims the dosing regimen used in Lo Loestrin as exemplified by its claim 1:

> A method of contraception comprising the steps of sequentially administering to a female of child-bearing age: (a) a first composition containing a progestin in an amount equivalent to about 0.3 to about 1.5 mg norethindrone acetate wherein the progestin is selected from norethindrone acetate or norethindrone and 5 to 15 mcg of ethinyl estradiol for 24 days; (b) a second composition containing 5 to 15 mcg of ethinyl estradiol and substantially free of a progestin for 2 days; and (c) a third composition that is a placebo, wherein the sequential administration of the first composition, the second composition and the third composition, is performed on a daily basis over a 28 day cycle.

17. In prosecution of the '984 Patent, Warner Chilcott faced a Final Rejection from the USPTO over, *inter alia*, Bayer's U.S. Patent No. 5,756,490 (the "'490 Patent"), which claims a continuous estrogen dosing regimen without placebo tablets.

18. The USPTO Examiner found the ’984 Patent claims obvious because he believed it would be obvious to insert placebo tablets into the continuous estrogen regimen of the Bayer ’490 Patent because “breaks in steroid administration are common in the oral contraceptive art … [t]hus, the skilled artisan would recognize that placebo compositions can be incorporated in oral contraceptive methods without reducing the methods’ effectiveness …” and also that “[t]he art worker would understand that a placebo can be administered given the prevalence of placebo phases in the oral contraceptive art.”

19. In response to this Final Rejection, Warner Chilcott distinguished the ’490 Patent by arguing that it does not disclose or suggest a placebo period, stating “a person of ordinary skill in the art would not have had a reasonable expectation of obtaining a successful contraceptive regimen by introducing a placebo period into a regimen of [the ’490 Patent] in view of [the ’490 Patent]’s teachings.”

20. Contrary to Warner Chilcott’s statements to the Examiner regarding the teachings of the prior art, the ’940 Patent, which shares two inventors with the ’490 Patent, discloses the introduction of a placebo period into the regimen of the ’490 Patent.

21. The ’940 Patent is prior art to the ’984 Patent

22. The USPTO did not consider the ’940 Patent during the prosecution of Warner Chilcott’s ’984 Patent and Warner Chilcott did not provide the ’940 Patent to the USPTO. Had the Examiner considered the ’940 Patent he would not have allowed Warner Chilcott’s ’984 Patent to issue because the claims of the ’984 Patent are obvious in light of Bayer’s ’940 Patent. The claims of the ’984 patent are not separately patentable over the ’940 Patent.

COUNT I - INFRINGEMENT
OF UNITED STATES PATENT NO. 5,980,940

23. Bayer restates and realleges each of the assertions set forth in Paragraphs 1 through 22.

24. Warner Chilcott's manufacture, use, offer for sale, and/or sale of Lo Loestrin infringes one or more claims of the '940 Patent under 35 U.S.C. § 271 either literally or under the doctrine of equivalents. Bayer is entitled to recover from Warner Chilcott the damages sustained by Bayer as a result of Warner Chilcott's wrongful acts in an amount subject to proof at trial, including an amount not less than a reasonable royalty together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE Bayer respectfully requests that the Court enter judgment in its favor against Warner Chilcott, granting the following relief:

a. An adjudication that Warner Chilcott has infringed one or more claims of the '940 Patent either literally or under the doctrine of equivalents;

b. A grant of a permanent injunction pursuant to 35 U.S.C. § 283, enjoining Warner Chilcott and its agents, servants, officers, directors, employees, affiliated entities, and all persons in active concert or participation with them from continued infringement of the '940 Patent;

c. An award to Bayer of damages adequate to compensate Bayer for Warner Chilcott's acts of infringement of the '940 Patent;

d. An award of prejudgment and post-judgment interest on all sums awarded;

e. A post-verdict and post-judgment accounting for any infringement of the '940 Patent not otherwise covered by a damages award and the requested injunctive relief; and

f. Any such other and further relief as the Court may deem just and proper under the circumstances.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Bayer respectfully requests a trial by jury of any and all issues on which a trial by jury is available under applicable law.

August 13, 2012

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